



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

12/2

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/645,869 | 08/22/2003 | J. Frank Koenig | 7233 | 8644 |

7590 03/24/2005

SHLESINGER, ARKWRIGHT & GARVEY LLP
3000 SOUTH EADS STREET
ARLINGTON, VA 22202

EXAMINER

GILBERT, SAMUEL G

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/645,869 | KOENIG ET AL. | |
| | Examiner | Art Unit | |
| | Samuel G. Gilbert | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/16/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Disclosure Documents

The applicant referenced four disclosure documents and indicated copies were attached. The copies are not currently included in the file. The examiner requests that copies be submitted in response to this office action.

Information Disclosure Statement

The information disclosure statement filed 1/16/204 has been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 – the preamble of claim 1 calls for a method for diagnosing penile atherosclerosis as a primary cause for erectile dysfunction however the body of the claim does not set forth the step for making such a diagnosis. Therefore the metes and bounds of the claim is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wysor et al(6,183,414).

Wysor et al teach a method of momentary application of a vacuum to overcome male impotence.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wilson.

Wilson teaches a method of applying a momentary vacuum to obtain an erection.

Claims 1, 2, 6-8, 12-14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Baniel et al(Comparative evaluation of treatments for erectile dysfunction in patients with prostate cancer after radical retropubic prostatectomy.

Baniel teaches combined vacuum therapy and administered medication. Applicant's attention is directed to "Objective" on page 30,(from dialog a description of Baniel) for the four phase treatment regimen. Further, alprostadil is taught as PGE1, page 59.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5, 9-11 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Baniel in view of El-Rashidy. Baniel teaches vacuum therapy in combination with the use of a vasodilator such as, PGE1, but does not teach the use of sildenafil in combination with the vacuum therapy and vasodilators. El-Rashidy teaches the benefits of combined therapy of optimizing the efficacy of each drug and substantially minimizes the undesirable side effects associated with each drug individually. Column 4 lines 9-25, sets forth the combination of sildenafil and PGE1. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a combined drug therapy of sildenafil and PGE1 with the vacuum therapy of Baniel in place of the single drug therapy of Baniel to gain the advantages of optimized efficacy and reduced side effects of the drugs as taught by El-Rashidy

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6,455,564 and Cecchi et al. and Hubert et al. teach related drug therapies for erectile dysfunction treatment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenberg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Samuel G. Gilbert
Primary Examiner
Art Unit 3736

sgg